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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/591,651	02/12/96	CLASSEN J	CLASSEN=1A

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HM12/1105

EXAMINER	
BRUMBACK, B	
ART UNIT	PAPER NUMBER
1642	31

DATE MAILED: 11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/591,651	Applicant(s) CLASSEN, JOHN B.	
	Examiner Brenda G. Brumback	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2001 and 27 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *153-155,158,159 and 161-265* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,8,10,11,16,19,27-30,32-41,43,44,46,49-52,55-57,59-68,71-74,77-88,90-152,156,157 and 160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 5,6, 8,10,11,16,19,27-30,32-41,43,44,46,49-52,55-57,59-68,71-74,77-88 and 90-265.

DETAILED ACTION

1. This action is responsive to the amendments filed 08/17/2001 and 09/27/2001. Claims 69, 70, 75, 76, and 89 were canceled.

Claims 5, 19, 30, 32, 38, 40, 56, 67, 71, 73, 77, and 129 were amended.

New claims 144-265 were added.

2. Newly submitted claims 153-155, 158-159, and 161-265 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Claims 153-155, 158-159,161-258, and 260-261 are directed to methods of immunization comprising identifying first and second groups of mammals.

Claim 259 is directed to a method of simultaneous immunization for infectious disease and a chronic immune mediated disorder.

Claims 262-265 are drawn to business methods.

The originally presented claims were drawn to kits and methods for reducing the incidence or severity of a chronic immune-mediated disorder comprising immunizing a mammal. The methods of the above groups are different and distinct from the originally presented methods because they have different method steps, utilize different components, and have different outcomes.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 153-155, 158-159, and 161-265 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 5, 6, 8, 10, 11, 16, 19, 27-30, 32-41, 43, 44, 46, 49-52, 55-57 and 59-68, 71-74, 77-88, 90-152, 156-157, and 160 are under examination. Claims 6, 32, 33, 56-57, 101, 103, 106, 128-148, 156-157, and 160 are drawn to methods; claims 5, 8, 10, 11, 16, 27-30, 34-41, 43, 44, 46, 49-52, 55, 59-68, 71-74, 77-88, 90-100, 102, 104, 105, 107-127, and 149-152 are drawn to kits. Claim 19 is drawn to an immunogenic agent.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. The objections to claims 6, 19, 32, 56, 58, 67, 69, 70, and 75-77 are withdrawn pursuant to applicant's cancellation or amendment thereof.

The objections to claims 5, 30, 56-57, 67, 71, and 73 for informalities in nomenclature are maintained for the reasons of record and for the reasons outlined *infra*. Newly added claims 144, 150, 152 are also objected to for informalities in nomenclature.

Claims 5, 30, 56, 67, 73, 144 recite hepatitis A and/or hepatitis B as a disease. The terms "hepatitis A" and "hepatitis B" are used in the art to designate etiologic agents which cause the disease hepatitis, rather than the disease itself.

Claim 71 recites BCG as a disease; BCG is an art recognized abbreviation for an attenuated organism used in a vaccine, not for any particular disease.

Claims 149-150 recite herpes as a disease; the term "herpes" is normally used to designate one of a specific group of viruses, rather than a disease per se.

The term "typhu" in line 6 of claim 152 appears to be a typographical error for "typhus".

Correction is required.

Claim Rejections - 35 USC § 112

5. The rejection of claims 19 and 48 under 35 U.S.C. 112, second paragraph, is withdrawn pursuant to applicant's amendment or cancellation thereof.

The rejection of claims 5, 6, 8-11, 16, 27-30, 34-47, 49-57, 77, and 86 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant has questioned whether claims 6 and 57 are included in the present rejection under 35 U.S.C. 112, second paragraph. They are included for the reasons of record in Paper #25 (pages 3-4). Applicant argues that failure to provide explicit antecedent bases does not always render a claim indefinite. The examiner maintains that in the present case, the failure to provide

sufficient antecedent bases does render the claim indefinite because the scope of the claim is not ascertainable, as currently written. Correction is required.

Applicant's amendment of claim 40 to add a lower limit to the range is acknowledged; however, claim 40 remains rejected under 35 U.S.C. 112, second paragraph, for the reasons of record pertaining to the relative term, "substantially".

Applicant continues to argue that defining an immunogen by an associated disease is not indefinite because it encompasses any immunogen associated with any organism that causes the disease. Absent disclosure of the specific immunogens claimed, however, the claims remain indefinite because the skilled artisan would not be apprised of the metes and bounds of the claimed invention.

New Grounds of Rejection:

6. Claims 5, 30, 32, 67, 71, 73, 77-85, 144-152, 156, and 157 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 30, 32, 67, 71, 73, 77-85, 144, 149, 150, 151, and 152 recite "an immunogen of an organism" which causes one of a group of specifically recited diseases. The specification fails to teach what organisms are the etiologic agents of the recited diseases and fails to teach what is encompassed within an immunogen of the organism. Absent such disclosure, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite.

The term "substantially" in claims 144, 145, and 147 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 146 recites a total dosage during the first 112 days after birth which is greater that required for immunization against the infectious disease with which it is associated. The specification fails to teach what diseases are associated with immunogens, fails to teach the metes and bounds of the dosage required for immunization against an associated disease, and fails to teach what is encompassed within a greater total dosage. Absent such disclosure, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Claim 148 recites a state of maturation in a mammal comparable to that achieved at an age of 42 days after birth in a mouse or rat. The specification fails to teach such a state of maturation in any mammals other than the mouse or rat, fails to defines the parameters of the state of maturation in the mouse and rat to be used as a benchmark for comparison, and fails to define how a state of maturation in a mammal other than a mouse or rat is to be measured and compared to that of the mouse or rat.

The phrase "the maximum interval between administrations is about two weeks or less" in claim 148 renders the claim indefinite, as the lower limit of the claimed range cannot be ascertained.

Claims 149-152 recite "flavivirus antigens". This phrase renders the claims indefinite as the specification fails to disclose the specific viruses and antigens of the viruses which are encompassed. Absent such disclosure, the metes and bounds of the claimed invention cannot be determined and the claims are indefinite.

Claims 150-152 are indefinite for being in improper Markush format, in that the claims recite a Markush group within a Markush group. As a result, the parameters of the claimed invention cannot be ascertained.

Claims 156 and 160 are indefinite as depending from canceled claims. Correction is required.

Claim 157 is indefinite for improper dependency. Claim 157 recites the "method of claim 5"; claim 5 recites a kit, not a method. Correction is required.

7. The rejection of claims 5, 6, 8, 10-11, 16, 30, 32, 38, 49, 55-57, 59-65, 72, and 74-101 under 35 U.S.C. 112, first paragraph, for new matter is maintained for the reasons of record.

Applicant's arguments on pages 19-22 are noted; however, they are not persuasive for reasons which have been previous outlined (see Paper # 28, pages 5-6). Applicant's arguments filed with the present amendment do not point out where support for newly added material is found.

New Grounds of Rejection:

8. Claims 40 and 145-148 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following portions of the claims do not appear to enjoy support in the disclosure: Claim 40 (last line), "at least one", claim 145 (last two lines), "wherein at least one immunogen ... four different dates ... after birth"; claim 146 (last four lines), "the total dosage during ... with which it is associated"; claim 147 (last three lines) "wherein at least one immunogen ... immunogen are administered"; and claim 148 (lines 10-13 and 23-27) "the first dose of said immunization schedule ... after birth in a mouse or a rat" and "one or more immunogens are administered ... or less". These matters might be resolved if applicant were to point out specifically where in the disclosure support for the newly recited material can be found.

9. The rejection of method claims 5, 6, 8, 10, 11, 15, 16, 19, 27-30, 32-41, 43, 44, 46, 49-52, 55-57, 58-101, 103, 106, and 128-143 under 35 U.S.C. 112, first paragraph, as not enabled is maintained for the reasons of record.

Applicant's arguments regarding this rejection have been fully considered but they are not persuasive for the reasons outlined in Paper # 28 and also for the additional reasons which follow.

Regarding utility, applicant's argument is noted; however, the present claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons outlined in Paper #25 (see pages 7-12). They are not presently rejected as lacking utility.

Applicant's arguments pertaining to claims 102, 104, 105, and 107-127 are noted; however these claims are not presently rejected under 35 U.S.C. 112, first paragraph. Therefore, the arguments do not appear to be germane to the present grounds of rejection.

Applicant's arguments regarding epidemiological data and extrapolation of data from mice to humans have been previously addressed. Applicant's submission of the Classen and Classen reference which discusses the mouse model is noted; however, absence evidence to the contrary, the reference would seem to teach away from enablement of the present claims, as it teaches a correlation between an increased risk of IDDM (a chronic immune-mediated disorder) and immunization.

10. Newly added claims 144-152, 156, 157, and 160 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record and for the additional reasons which follow.

The factors to be considered in determining enablement, the state of the art, and the lack of sufficient guidance in the specification to overcome the teachings of unpredictability found in the art have been set forth in a previous Office action (See Paper # 25, mailed 6/20/2000). Additionally, claim 145 recites a total dosage of an immunogen greater than that required for immunization against the infectious disease with which it is associated. As has been previously set forth herein, the specification fails to teach the infectious diseases which are associated with the claimed immunogen, fails to teach the parameters of the total dosage of the claimed immunogen required for immunization against the associated disease, and fails to teach how much greater dosage is required for reducing the incidence of severity of a chronic immune-mediated disorder. As was pointed out in a previous Office action (Paper # 25, pages 9-10), while the art teaches effective immunization against infectious diseases by administration of specific immunogens, the art does not teach effective dosages of an immunogen for reducing the incidence or severity of a chronic immune mediated disorder. Because the disclosure does not provide sufficient guidance regarding effective immunization dosages for chronic immune-mediated disorders, one of skill in the art would be unable to practice the claimed invention absent undue experimentation. Furthermore, one of skill in the art would be unable to make the kits of claims 149-152 comprising "flavivirus antigens" without disclosure of specific flavivirus antigens to be encompassed within the kits absent undue experimentation. The art does not teach any specific flavivirus antigens which reduce the incidence or severity of a chronic immune

mediated disorder and the specification fails to provide teachings of sufficient detail to overcome the teachings of unpredictability found in the art.

Claim Rejections - 35 USC § 101/ Double Patenting

11. The rejection of claims 2-4, 16-17, 19, 21, 23-25, 27-21, 24-47, 49-55, and 101-127 is withdrawn pursuant to cancellation of the claims or applicant's arguments, which were persuasive.

The rejection of claims 6, 32-33, 56-57, 101, 103, 128-143 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of Classen U.S. Patent No. 5,728,385 and claims 1-47 of Classen U.S. Patent No. 5,723,283 is maintained for the reasons of record.

Newly added claims 144-148, 156, 157, and 160 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of Classen U.S. Patent No. 5,728,385 and claims 1-47 of Classen U.S. Patent No. 5,723,283 is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

12. The rejection of claims 8, 10, 11, 16, 27-30, 34-41, 43, 44, 46, 49-52, 55, 59-67, 72, 73, 77, 79, 90, 92, 96-100, 102, 104, 105, and 107-127 under 35 U.S.C. 102(b) as being anticipated by Madore et al. and the rejection of claims 5, 8, 10, 11, 16, 19, 27-30, 32-41, 43, 44, 46, 49-52,

59-67, 71-73, 78, 79, 90, 92, 93, 96-100, 102, 104, 105, and 107-127 under 35 U.S.C. 102(b) as anticipated by Madore et al. or John, are withdrawn pursuant to applicant's arguments, which were persuasive.

The rejection of claims 5, 6, 8, 10, 11, 16, 19, 27-30, 32-41, 43, 44, 46, 49-52, 59-67, 71-73, 78, 79, 90-93, 96-100, 102, 104, 105, and 107-127 under 35 U.S.C. 102(b) as anticipated by Halsey et al.; the rejection of claims 5, 6, 8, 10, 11, 16, 19, 27-30, 32-41, 43, 44, 46, 49-52, 60-67, 72, 73, 78, 79, 90, 91, 96-100, 102, 104, 105, and 107-127 under 35 U.S.C. 102(b) as anticipated by John; and the rejection of claims 5, 8, 10, 11, 16, 19, 27-30, 34-41, 43, 44, 46, 49-52, 55, 59-68, 71-74, 77-88, 90-100, 102, 104, 105, and 107-127 under 35 U.S.C. 102(b) as being anticipated by Benveniste and Lagrange et al. are all maintained for the reasons of record.

Newly added claims 149-150 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Madore et al., Dengrove et al., Halsey et al., or Benveniste and Lagrange et al. for the reasons of record.

Newly added claim 151 is rejected under 34 U.S.C. 102(b) as being anticipated by any of Madore et al., Dengrove et al., Halsey et al., John, or Benveniste and Lagrange et al. for the reasons of record.

Newly added claim 152 is rejected under 34 U.S.C. 102(b) as being anticipated by any of Madore et al., Dengrove et al., Halsey et al., John, or Benveniste and Lagrange et al. for the reasons of record.

Applicant's arguments pertaining to labeling and an alleged functional relationship between the label and the composition have been previously addressed (See Paper # 28, pages 11-12).

Applicant's arguments regarding patents issued to others have also been previously addressed (see Paper # 28, page 12). It is well settled that whether similar claims have been allowed to others is immaterial. *In re Giolito,* 530 F.2d 397, 188 USPQ 645 (1976).

Regarding claim 19, it is noted that applicant's quotation of the claim (page 40) is inaccurate, as claim 19 was amended with the response of 08/17/2001. The claim is drawn to an agent comprising two or more immunogens. The terms"pediatric" and "nonpediatric" are interpreted as referring to immunogens which are typically administered during early childhood and immunogens which are typically administered at some time after childhood (see the Amendment filed 03/25/2001). Any of Dengrove, Halsey, or Benveniste and Lagrange teaches a vaccine composition comprising diphtheria, pertussis, and tetanus immunogens. Diphtheria and pertussis can thus be considered to be "pediatric immunogens" and tetanus can thus be considered to be either a "pediatric" or a "nonpediatric" immunogen, as this immunogen is routinely administered to both children and adults. Thus, the composition disclosed by any of Dengrove et al. Halsey, or Benveniste and Lagrange anticipates the claim.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
October 30, 2001

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